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Figure 1

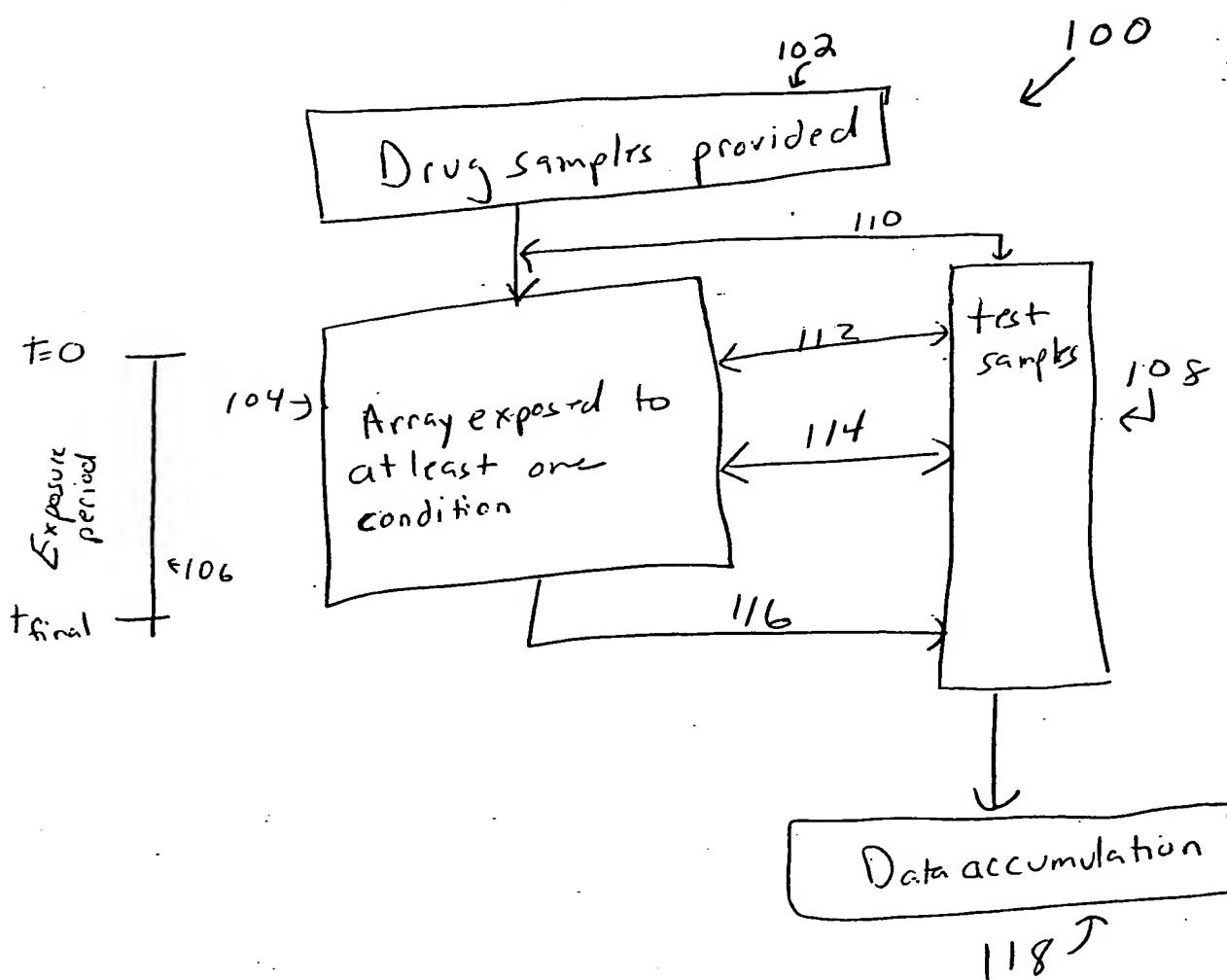
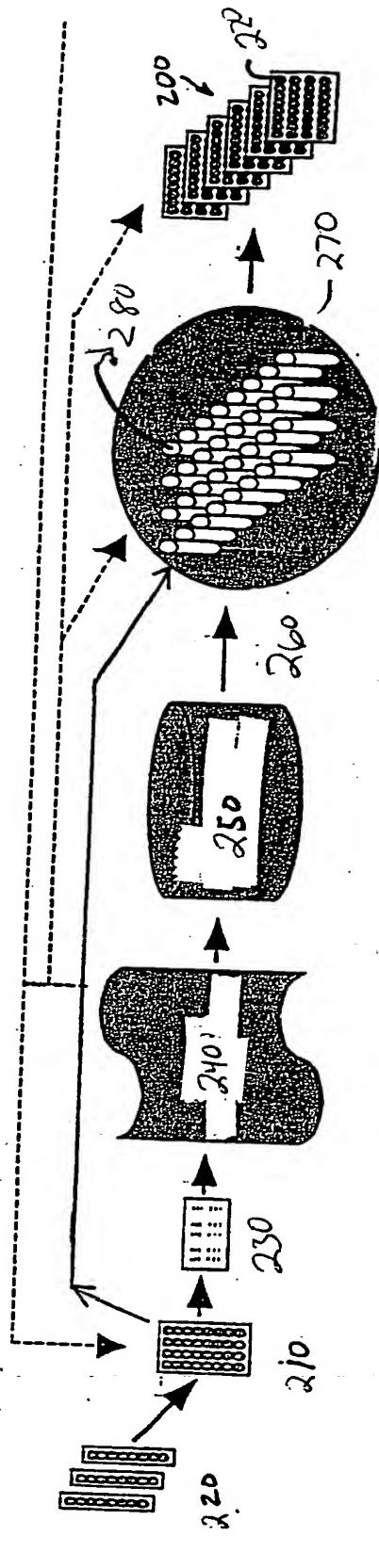
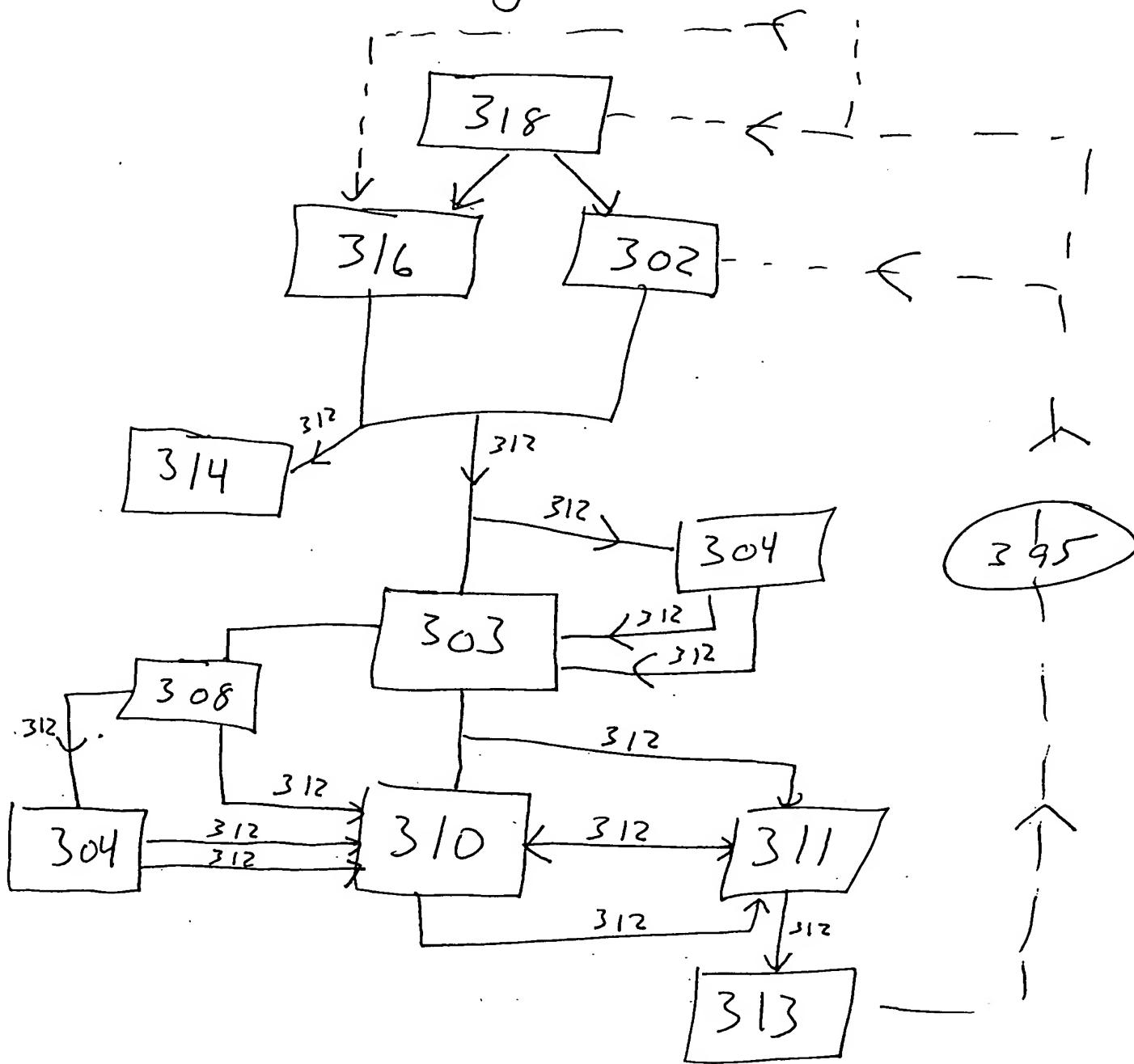


Figure 2

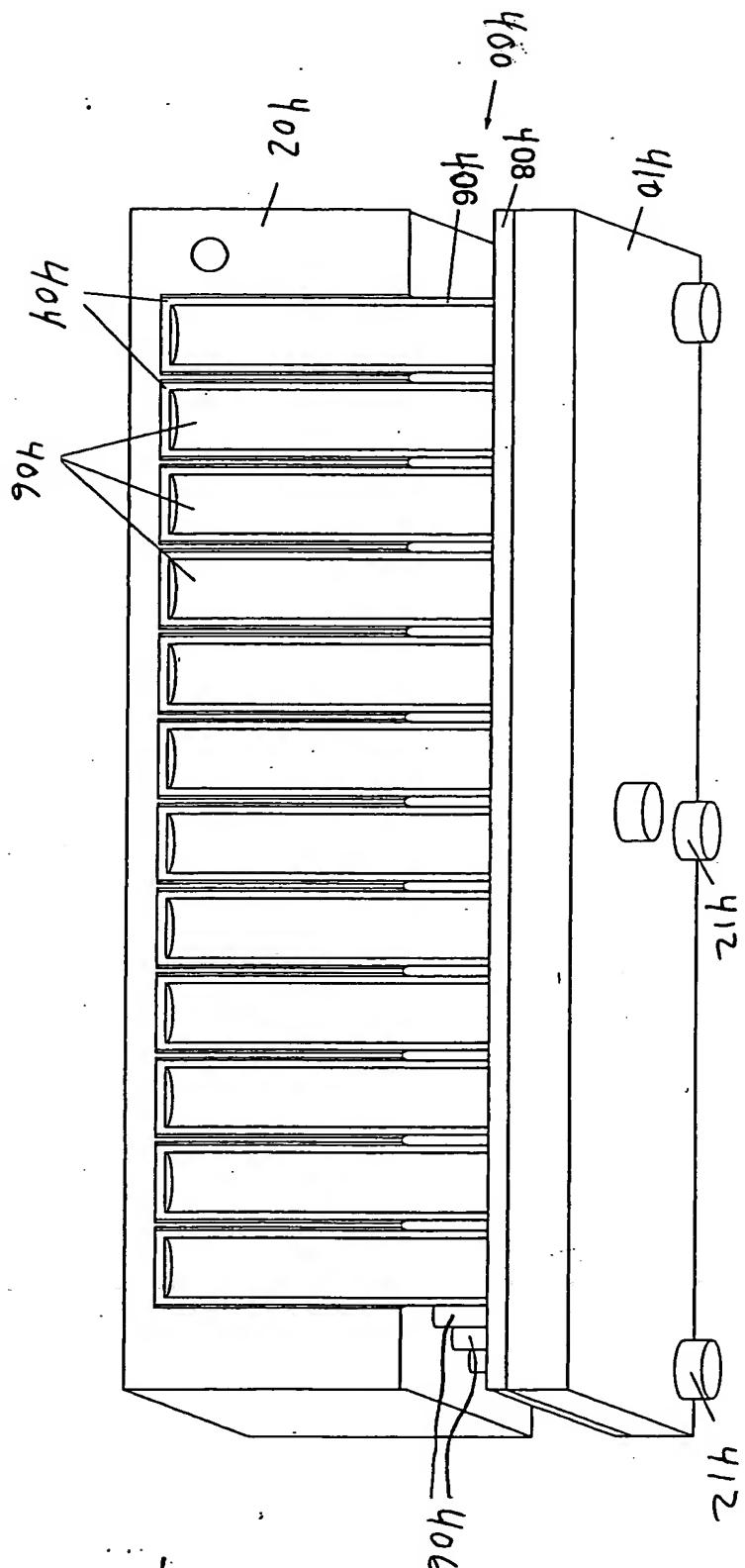


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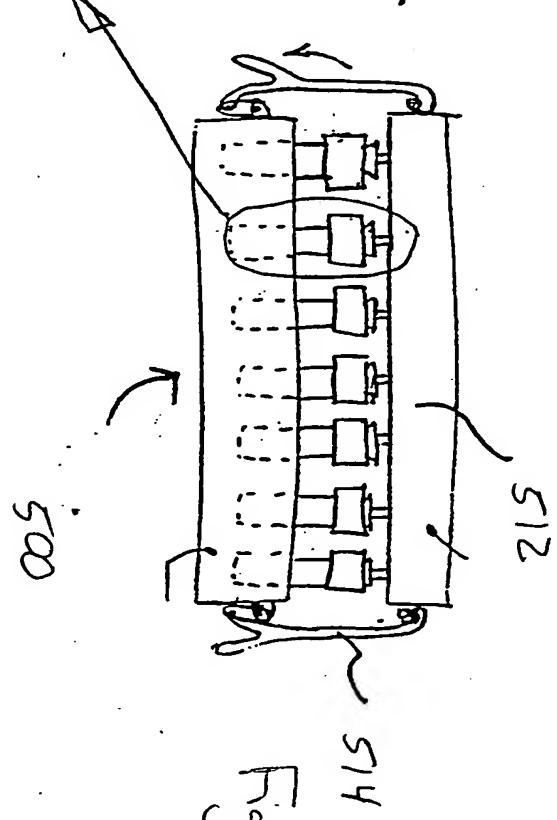
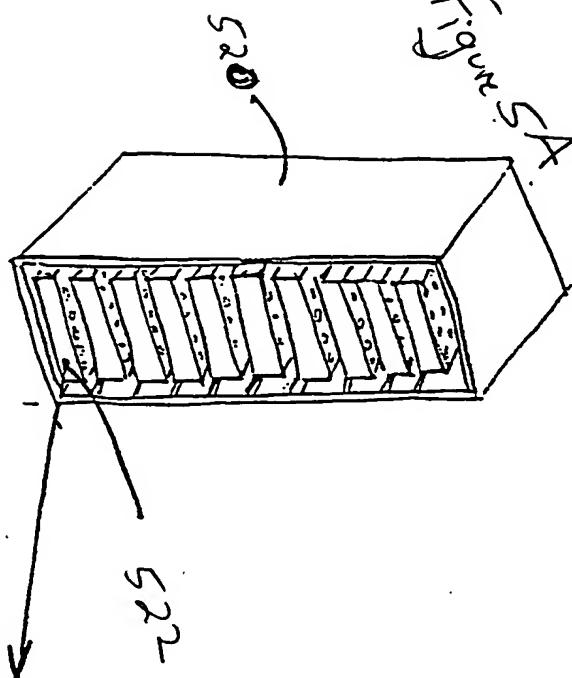
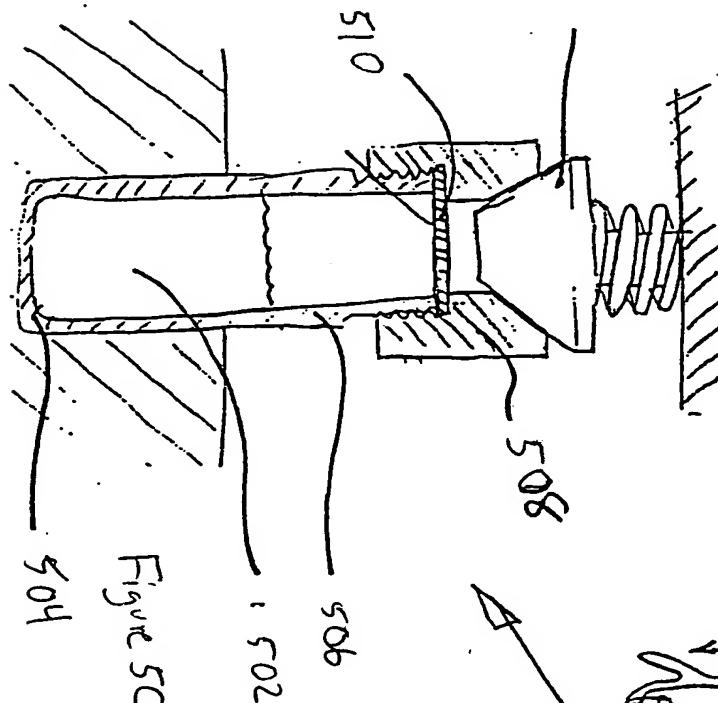
Figure 3



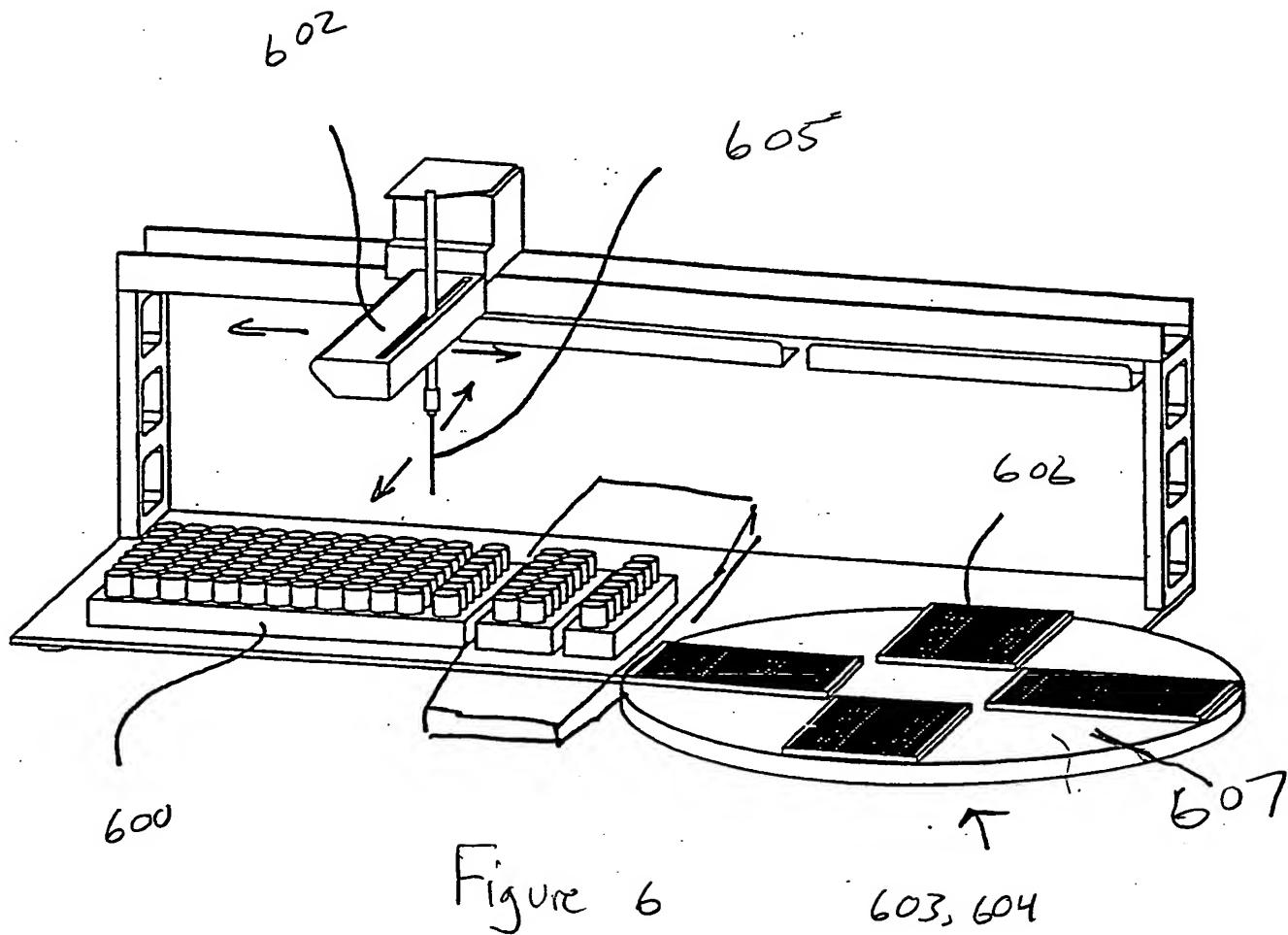
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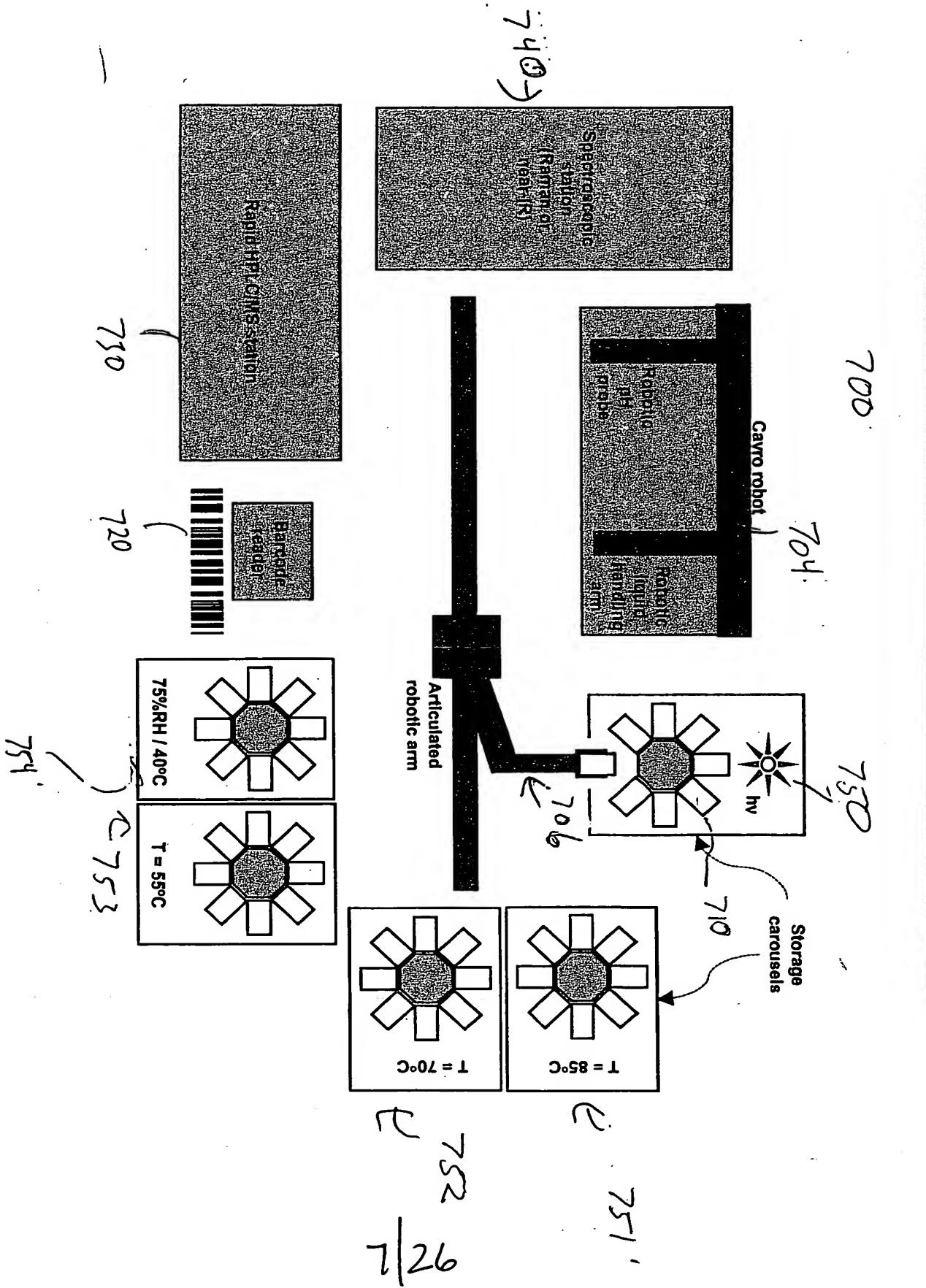


Figure 7

Figure 8A

Docket No. 2003-003R1 EMLN: EV186632526US
 Inventor: Carlson et al. Filed: March 1, 2004
 Title: Evaluating Effects Of Exposure Conditions On Drug Samples
 Over Time

	1	2	3	4	5	6	7	8	9	10	11	12
uncontrolled												
A	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	0.04 mg/mL
B												2.0 mg/mL
C												10.0 mg/mL
D												50.0 mg/mL
E												ethanol (20w/v)
F												propylene glycol (20w/v)
G												AlBN (1eq)
H												HOOH (1eq)

Aqueous solutions with a total volume of 800 μ L/well

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Excipient compatibility – solids formulations

Solids library 1: Diluents and Lubricants

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Excipient compatibility – solids formulations

Fixed diluent and lubricant with binders, glidants, colorants, acidifiers, alkylizers

	1	2	3	4	5	6	7	8	9	10	11	12	Colorant
A	1.0 mg	C.											[nothing]
B	7.0 mg	fixed diluent											[silicon dioxide]
C	0.2 mg	fixed lubricant											[nothing]
D													calcium silicate
E													talc
F													[nothing]
G													[silicon dioxide]
H	[nothing]	citric acid	mag. silicate	[nothing]	[nothing]	calcium	mag. oxide	[nothing]	calcium silicate	[nothing]	iron oxide	talc	[nothing]
I	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	propylene glycol
J	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	[nothing]	triethylmethylcellophane, sodium

DC = drug candidate

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Figure 4D

	1	2	3	4	5	6	7	8	9	10	11	12	
H													
G													
F													
E													
D													
C													
B													
A													
[δC] = 1 mg/ml		[δC] = 2 mg/ml		[δC] = 10 mg/ml		[δC] = 50 mg/ml		[δC] = 100 mg/ml		[δC] = 200 mg/ml		[δC] = 500 mg/ml	
1eq		2eq		5eq		1eq		2eq		5eq		1eq	
AIBN		HOOH		NaOH		HCl							

Total volume = 800 μ L/well
 δC = drug candidate

Liquids Samples

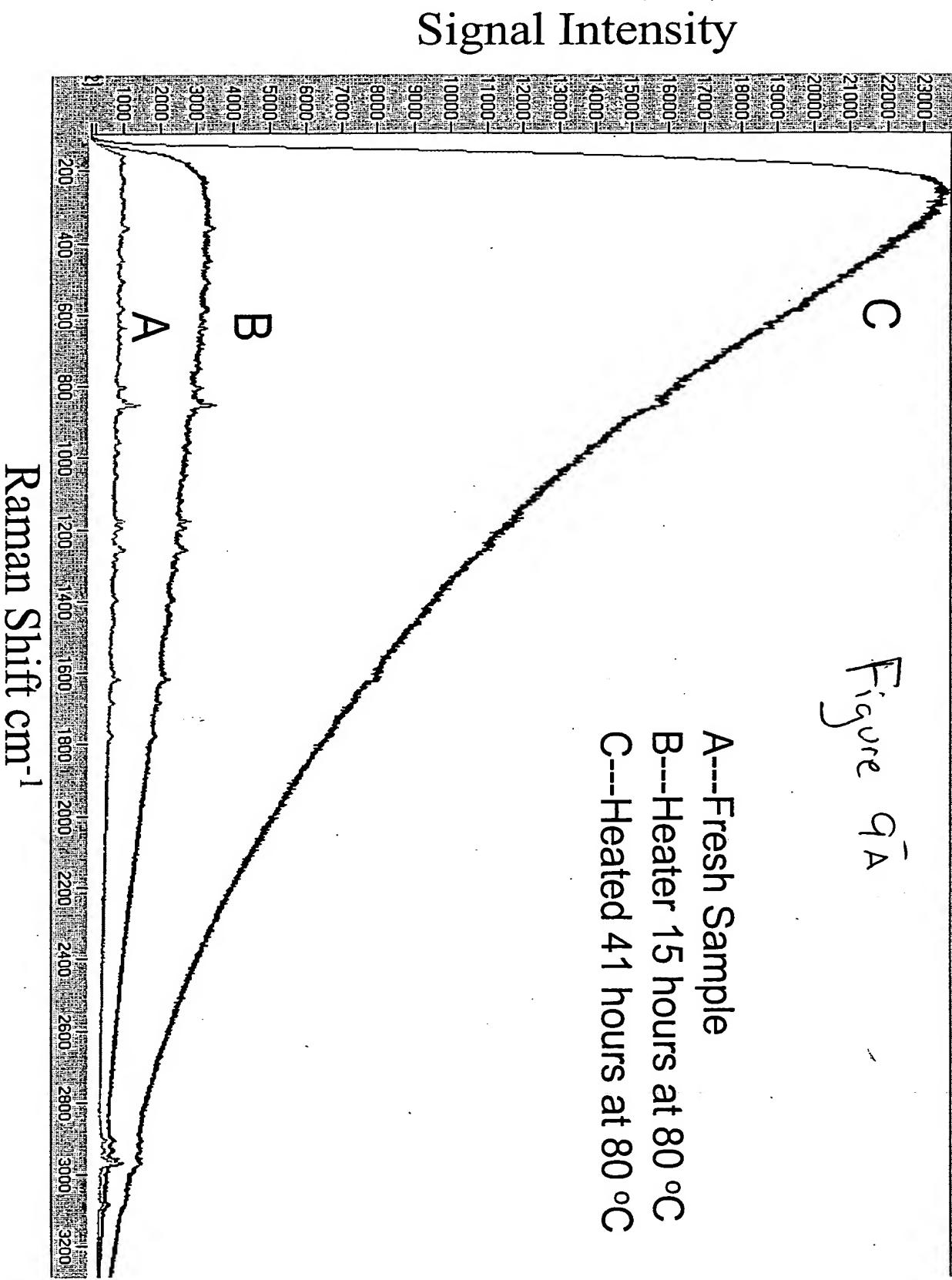
Chemical stability and excipient compatibility

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Stability of Amoxicillin by Fluorescence at 632.8 nm excitation

Figure 9A

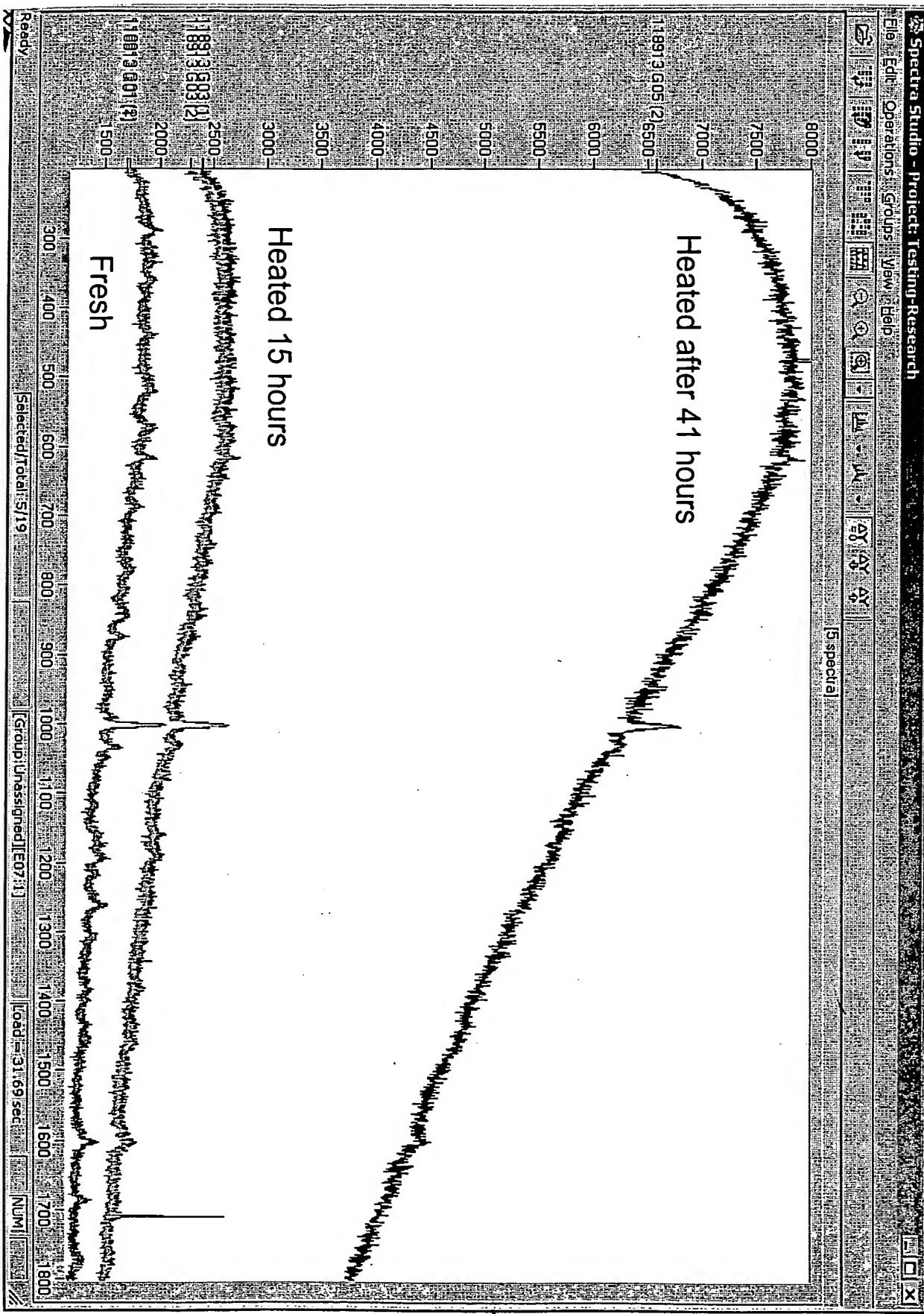
A---Fresh Sample
B---Heater 15 hours at 80 °C
C---Heated 41 hours at 80 °C



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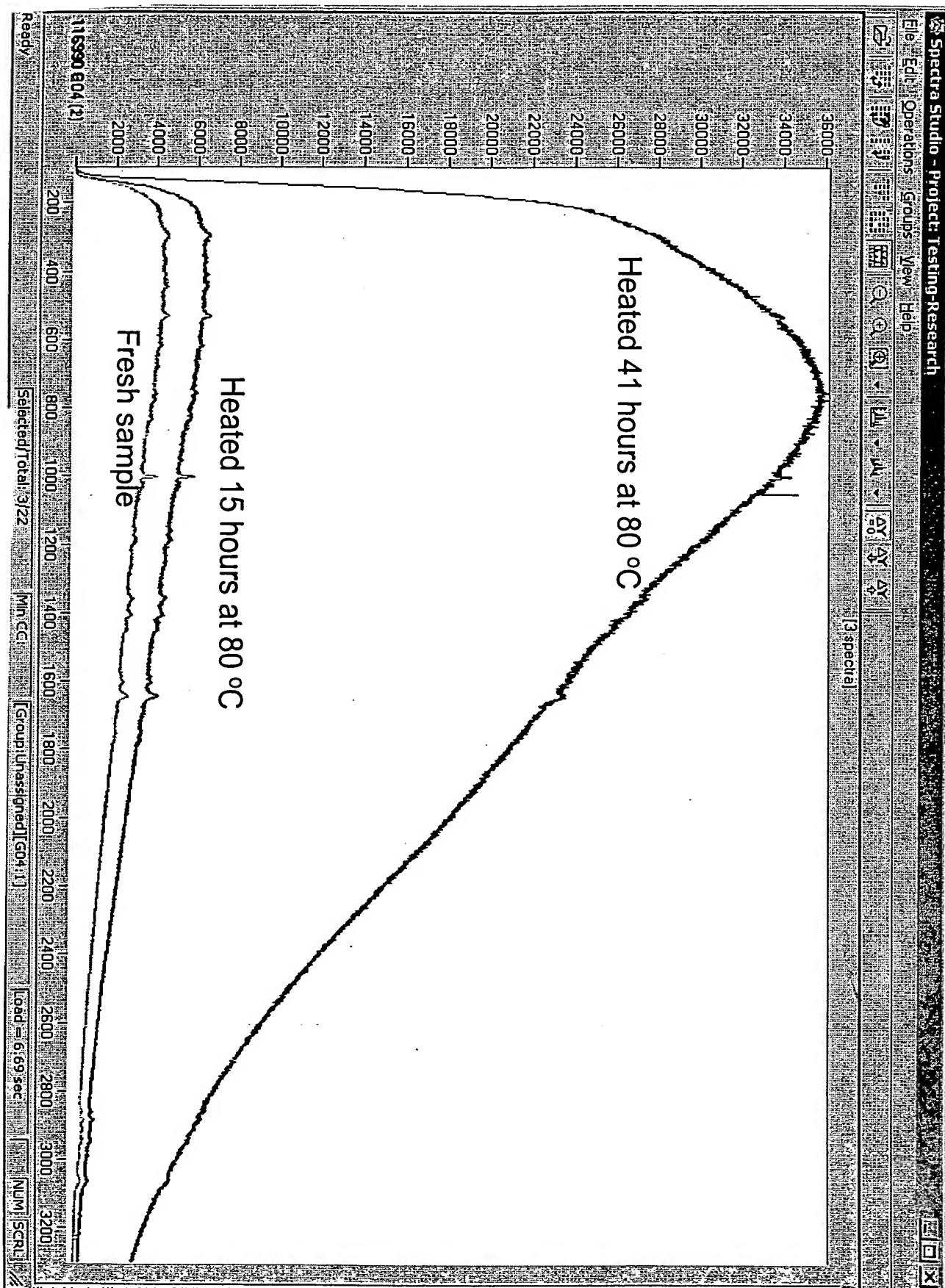
Fluorescence of Ampicillin tri-hydrate at 632.8 nm excitation

Figure 9B



Fluorescence of Cephalexin by 632.8 nm excitation

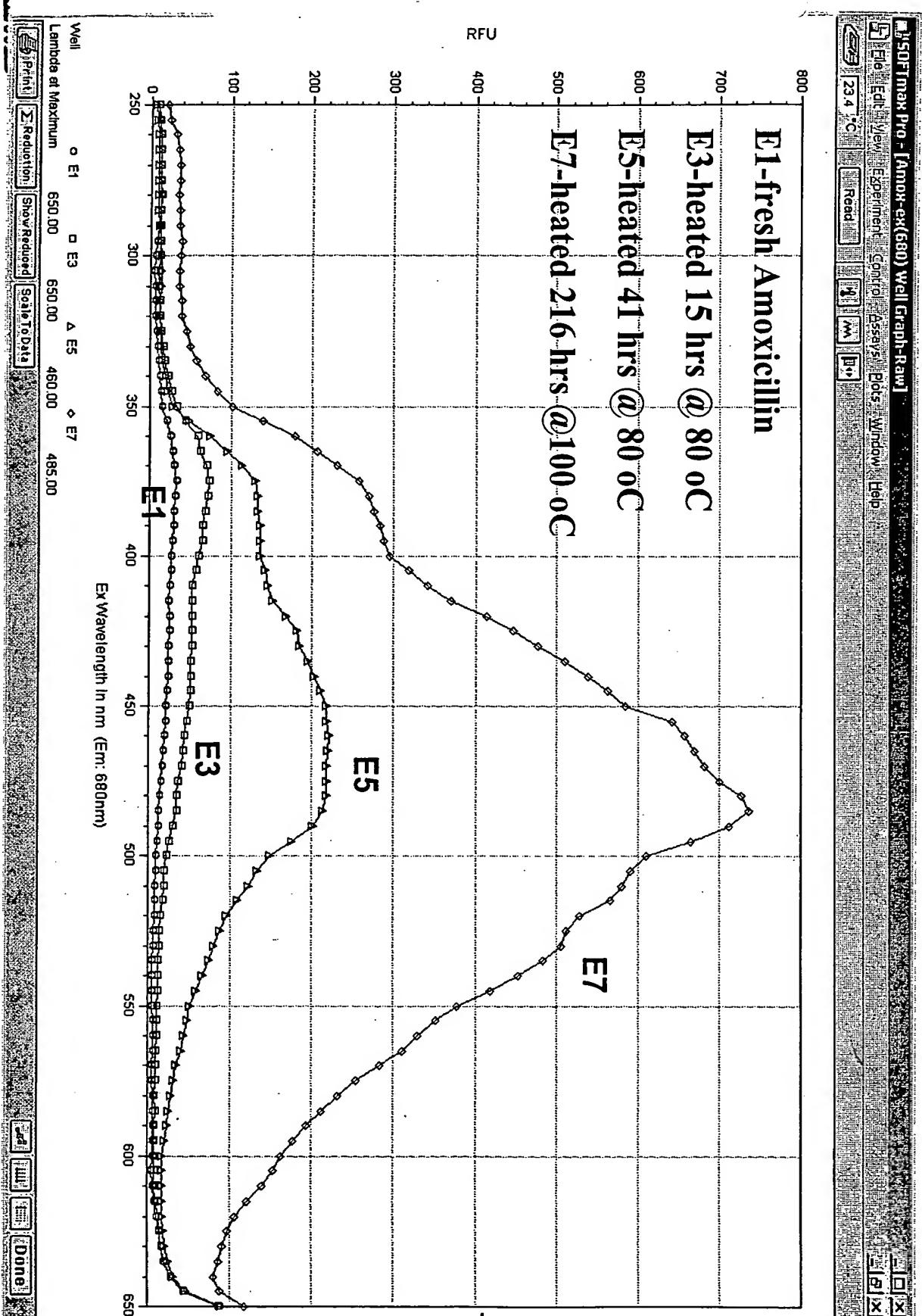
Figure 9C



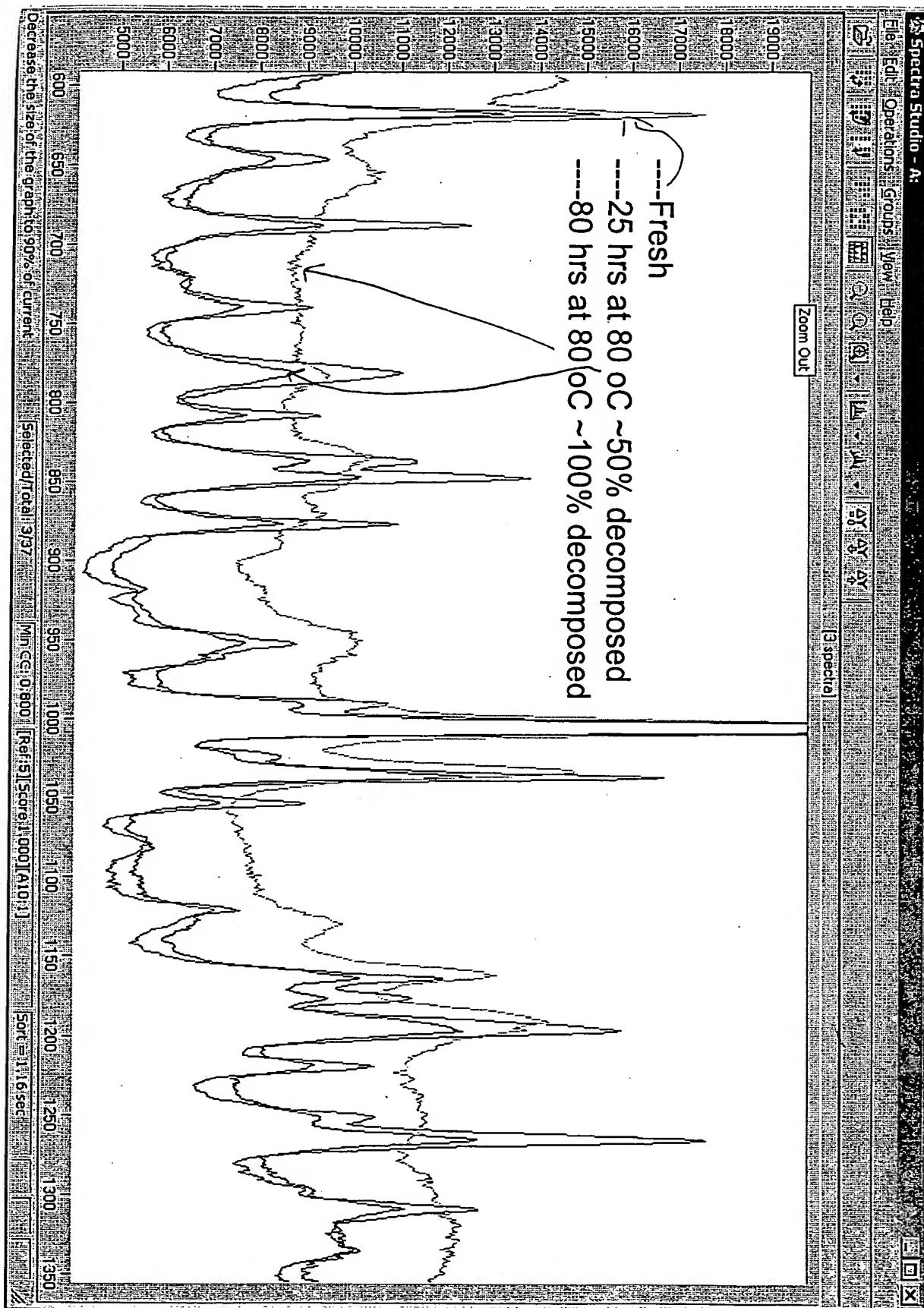
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Fluorescence Excitation Spectra of Amoxicillin & its decomposition Products by detecting at 680 nm

Figure 9D



Raman at 785 nm excitation: Ampicillin Trihydrate

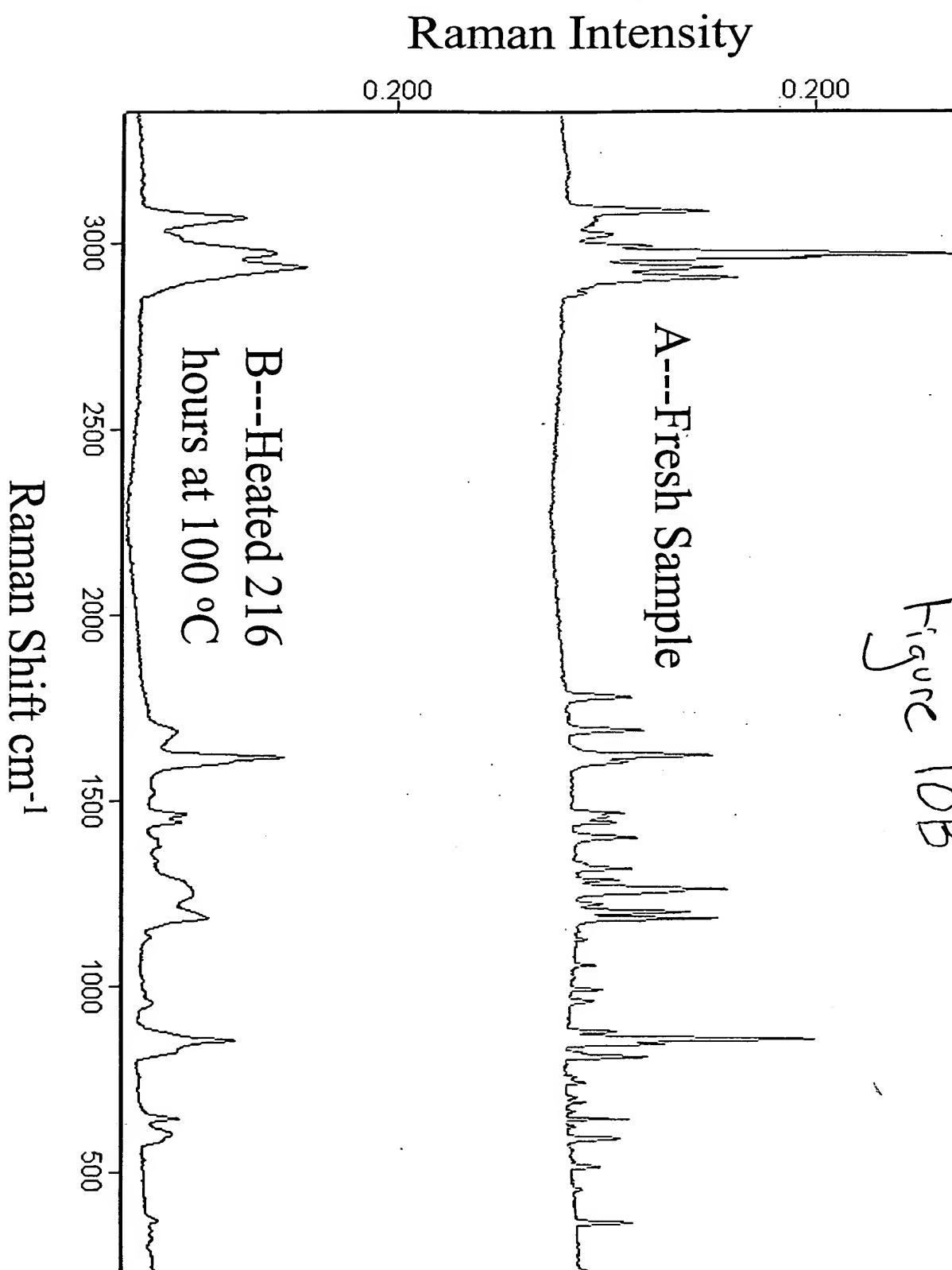


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Figure 10 A

Stability of Amoxicillin by FT-Raman at 1064 nm
excitation

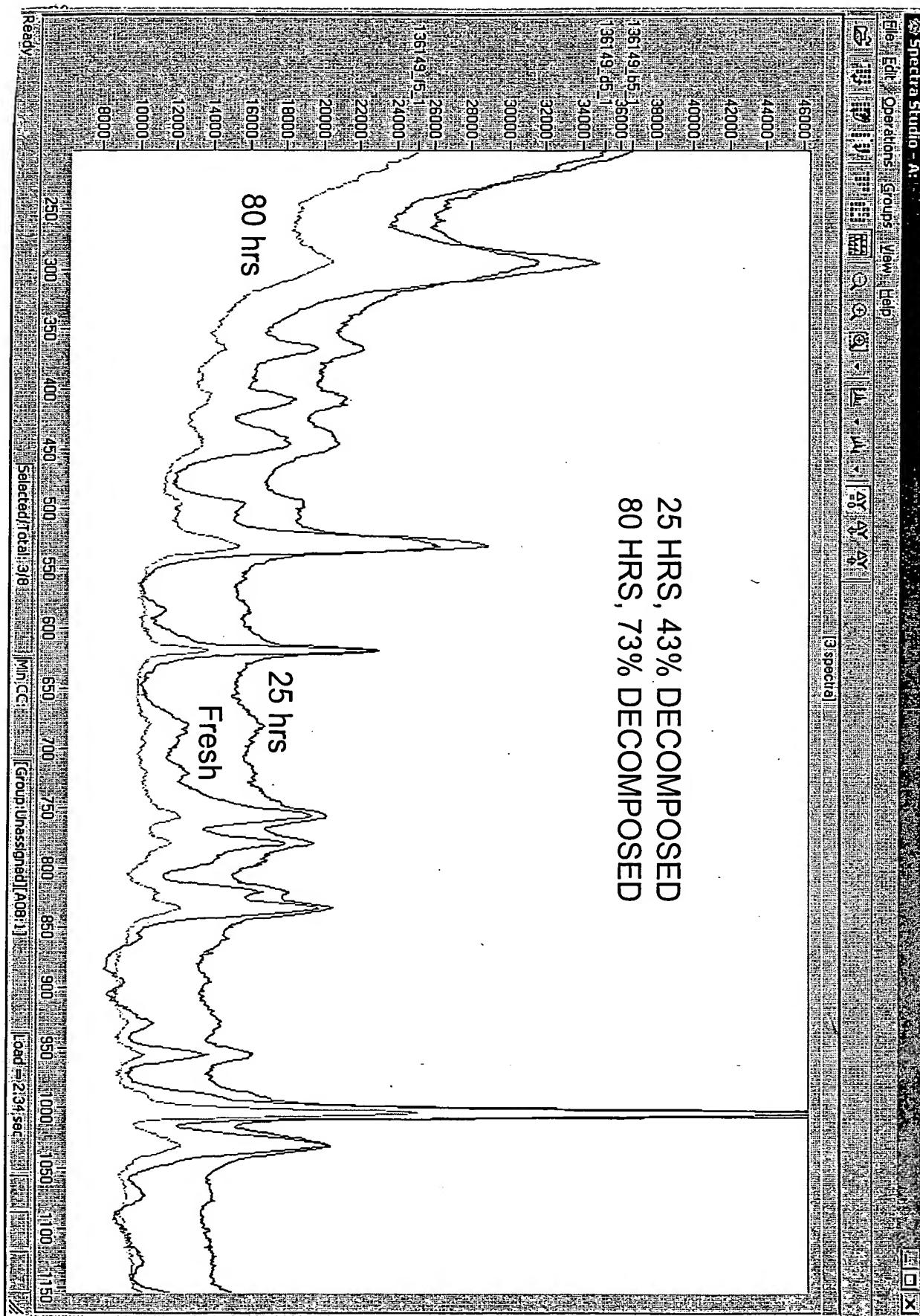
Figure 10B



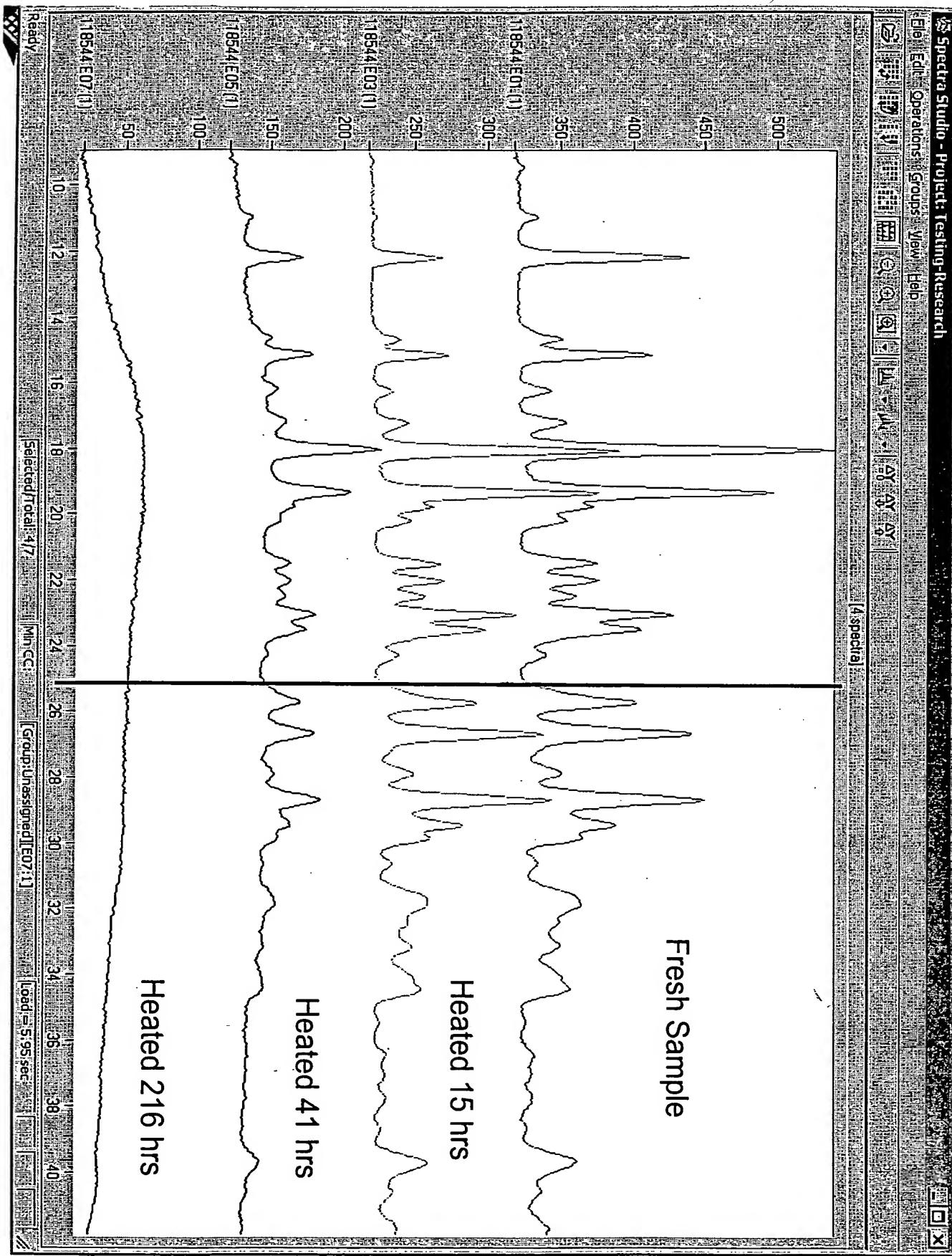
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Raman at 785 nm excitation: Cephalexin hydrate

Figure 10c



Stability of Amoxicillin after heating by XRD



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Figure 11

FTNIR of

amoxicillin powder

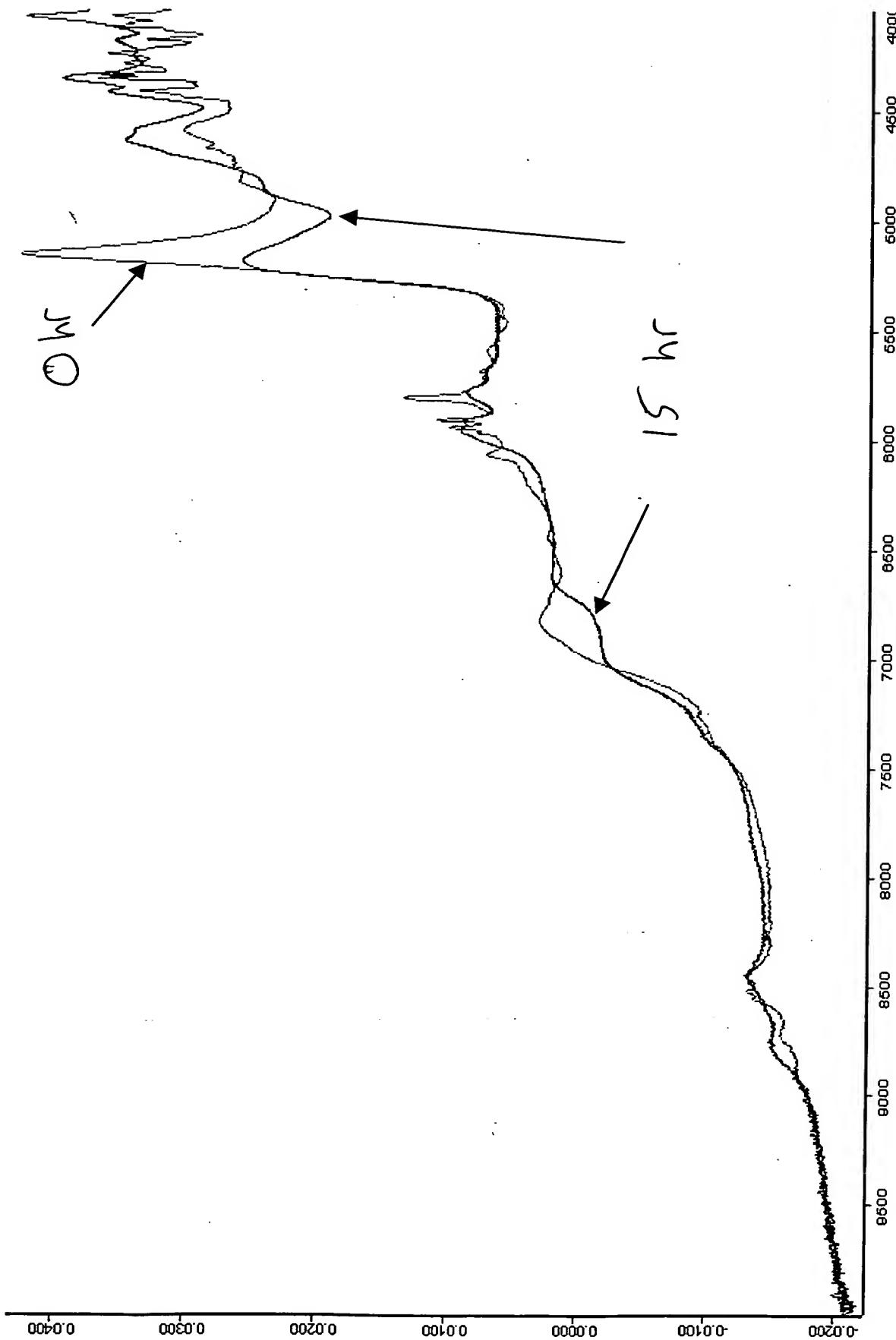


Figure 12 A

Docket No. 2003-003R1 EMLN: EV186632526US
Inventor: Carlson et al. Filed: March 1, 2004
Title: Evaluating Effects Of Exposure Conditions On Drug Samples
Over Time

FTNIR of Cephalexin powder in 8-mL vials after 0, 25, 80 hrs @ 80 oC.

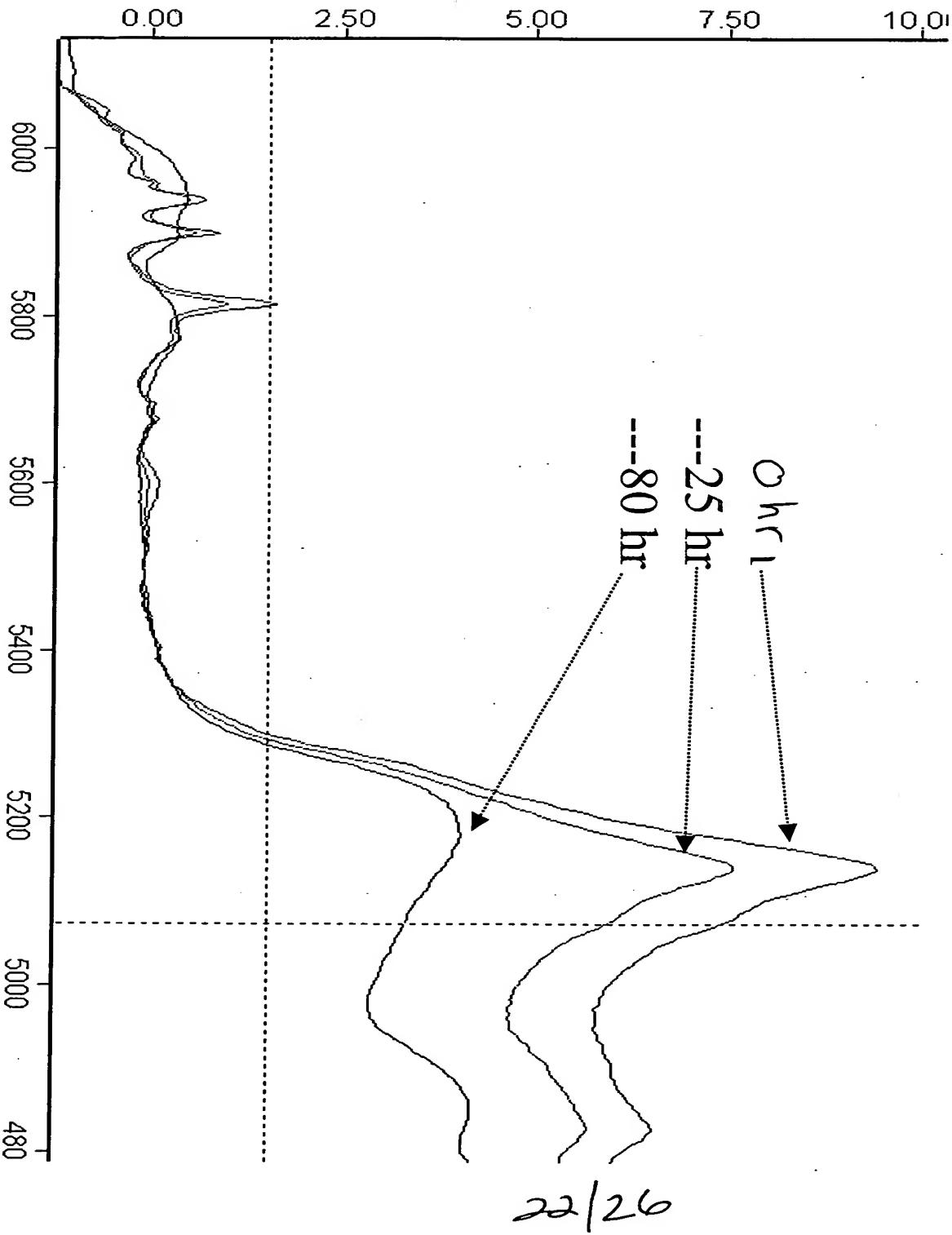


Figure 12/3

FTIR Diffuse Reflectance of amoxicillin and its 99.5%
decomposed powder after KM transform

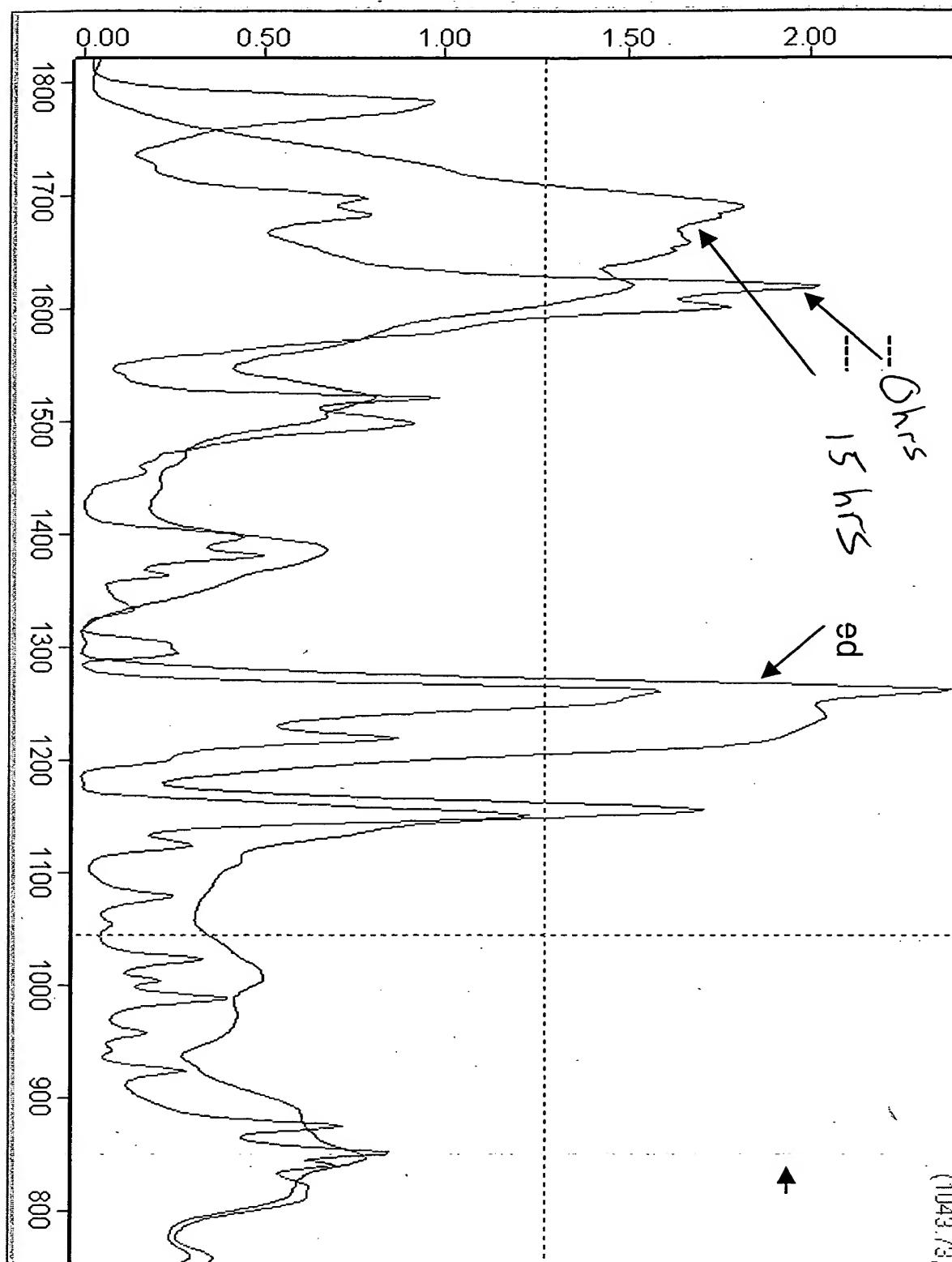


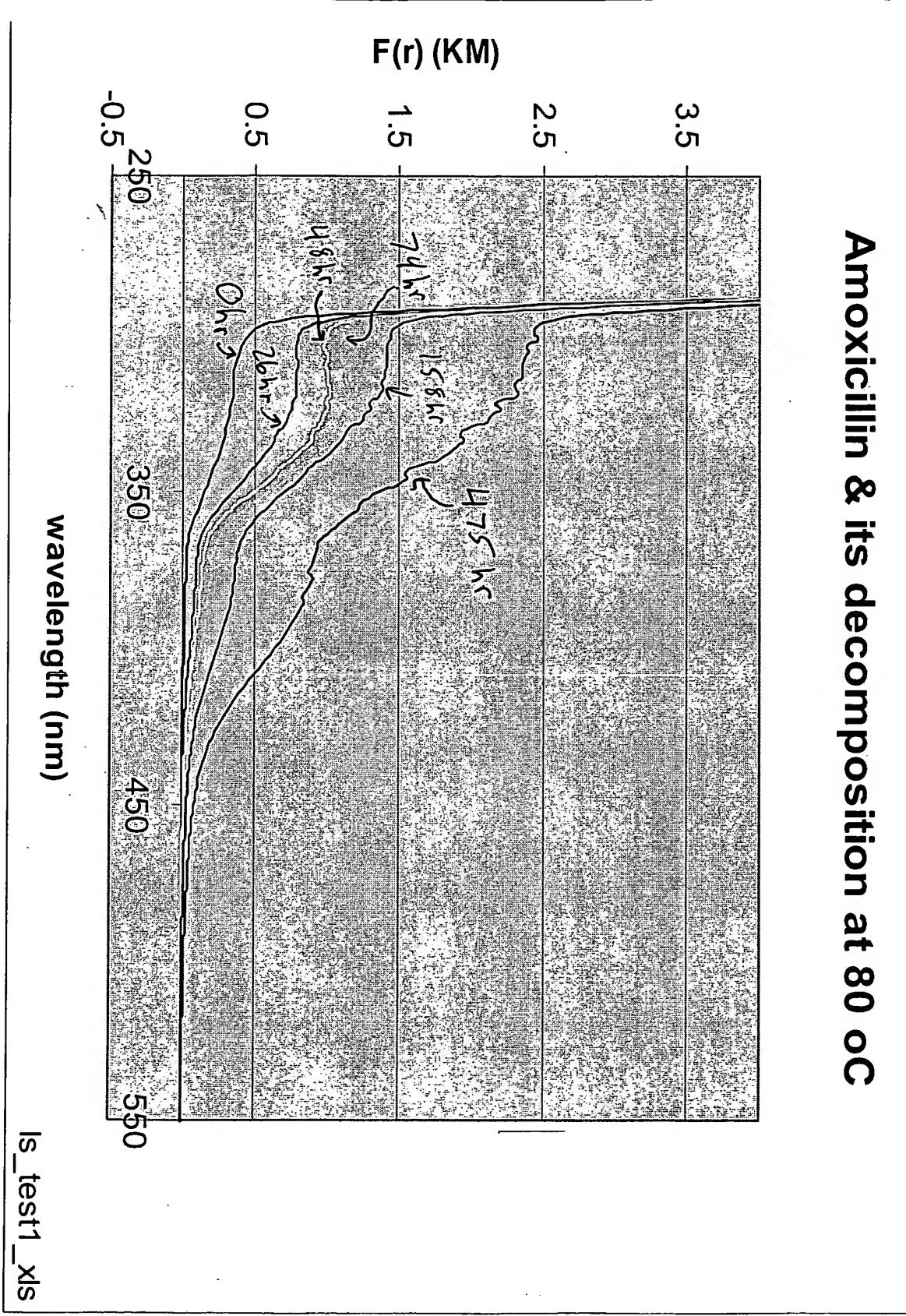
Figure 13

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UV-Vis diffuse reflectance measurement

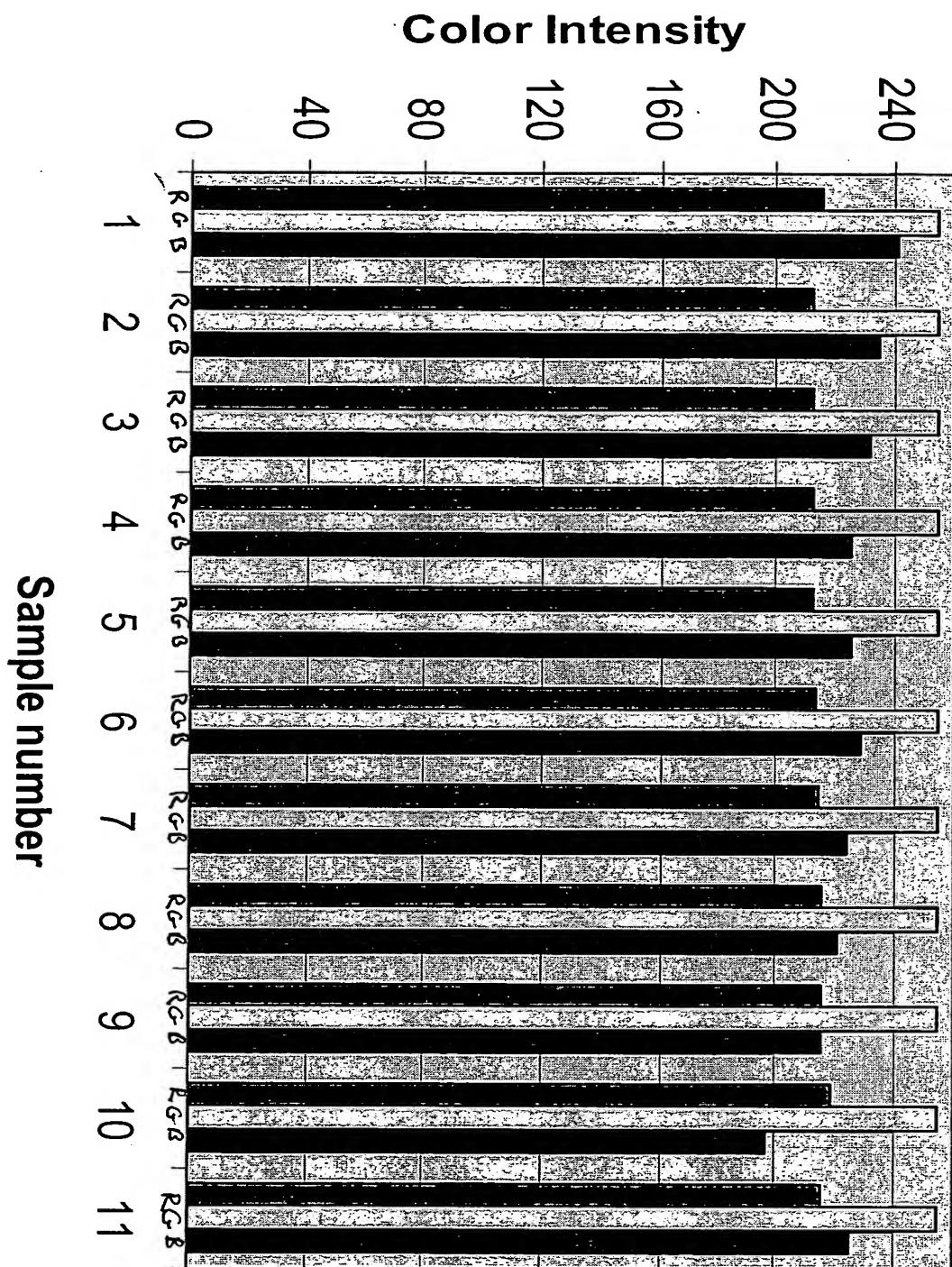
Amoxicillin & its decomposition at 80 °C

Figure 14



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ls_test1.xls

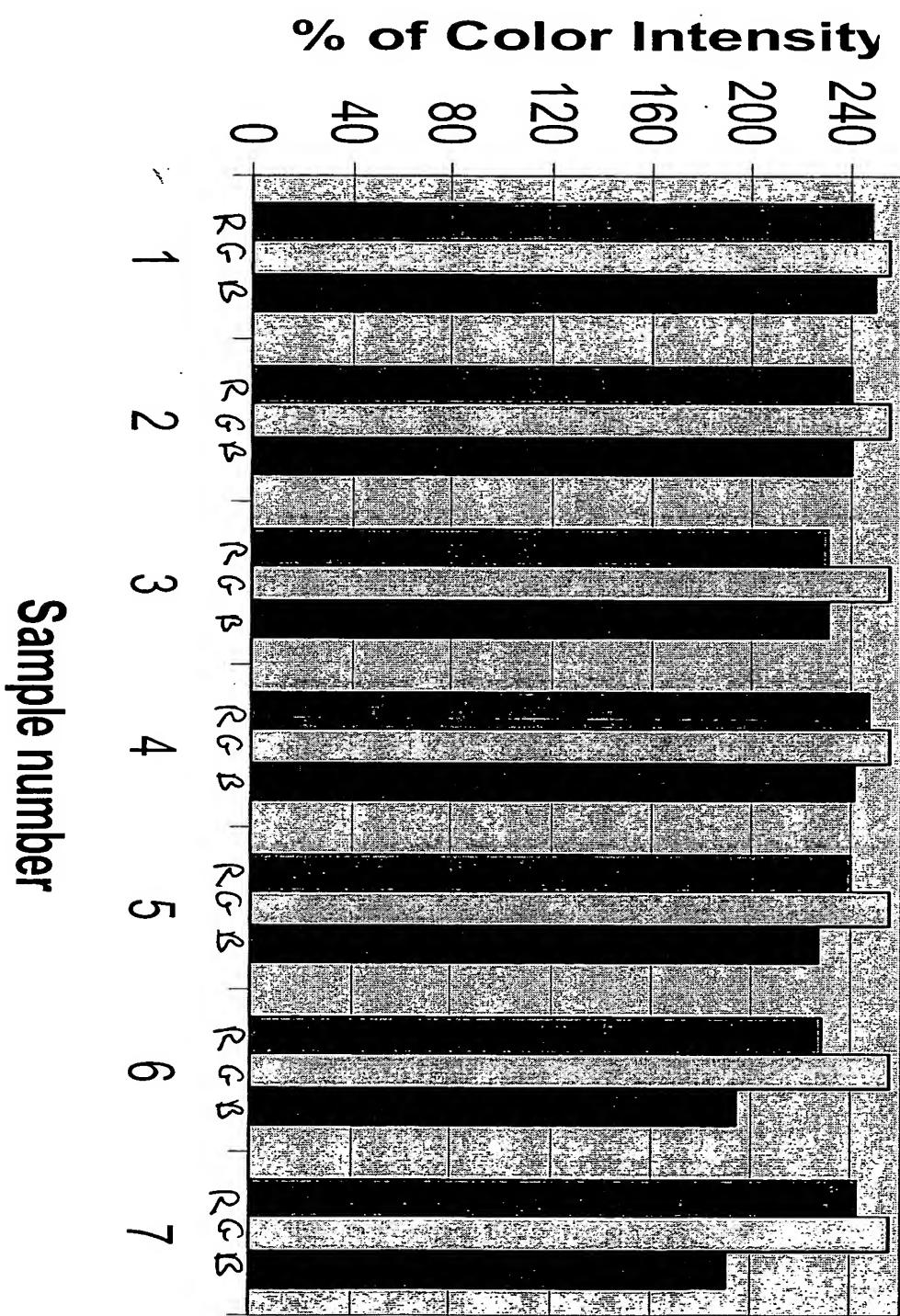


Colors of Amoxicillin Batch-1 Samples

Figure 15A

Color of Amoxicillin Batch-2 samples

Figure 15B



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